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REMARKS

Restriction Requirement

Applicants affirm the provisional election without traverse to prosecute the invention of Group I, claims 1 through 63, made during the telephone conversation between the Examiner and Dr. Salima Merani on January 17, 2006. Applicants acknowledge that Claims 64 through 95 have been withdrawn from further consideration by the Examiner as being drawn to a non-elected invention.

Amendments to Drawings

Applicants appreciate the Examiner's comments that some of the drawings do not include some of the references signs mentioned in the description. In response, Figures 20 and 21 have been amended to include reference signs 230, 231, 232 and 234 mentioned in paragraph [0077]. No new matter has been added with these drawing amendments, as paragraph [0077] describes in detail the thickness 230 of the septum wall 210 in Figure 20, the substantially thicker 231 wall of the septum 210 in Figure 21, and the distance 232 in Figure 20 between the proximal edge of the proximal ring 140 and the proximal surface of the septum wall 210, the greater corresponding distance 234 in Figure 21.

In Figure 22, Applicants have also amended reference sign 296 to 256 to correct an error. The structure identified is the "cylindrical body 256" as disclosed in paragraph [0080] discussing Figures 22-27, not the "return legs 296" which are disclosed in paragraph [0084] regarding Figures 28-30. No new matter has been added.

For purposes of clarity, Applicants have also amended the application by swapping the positions of Figures 29 and 30. Figures 29 and 30 are otherwise unchanged, and thus no new matter has been added.

Amendments to Specification

Applicants also appreciate that the Examiner has indicated that reference character "225" has been used to designate both a distal radiopaque marker and a catheter. Paragraph [0086] has been amended so that the reference character for the catheter is now "220". The use of "220" for

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the catheter is consistent with the catheter references in portions of paragraph [0086], and also paragraphs [0074-0076], [0087] and [0090]. No new matter has been added.

The Examiner also pointed out that reference character “210B” is shown in Figure 21 but not mentioned in the description. Paragraph [0077] has been amended so that references to the septum wall in Figure 21 have corrected from “210” to “210B” as intended in Figure 21. No new matter has been added.

Amendments to Claims

Independent Claim 1 recited an implantable device comprising a proximal anchor having at least one helical leg between a proximal ring and a distal ring. As recommended by the Examiner, Applicants have amended Claim 1 to positively recite the proximal ring and the distal ring. Applicants have also amended Claim 1 to further recite that the at least one helical leg extends from the proximal ring and the distal ring. No new matter has been added as support for the at least one helical legs depicted, for example, in Figures 20 and 21 extending from the proximal ring and the distal ring.

Independent Claim 33 recited a system for diagnosing and/or treating a condition in a patient, the system comprising an implant, a proximal anchor, a distal anchor, and a delivery catheter, wherein the proximal anchor and the distal anchor are configured to sandwich an atrial septum wall. Applicants have amended Claim 33 to recite that the at least one helical leg comprises a proximal base and a distal end, and that the proximal anchor and distal anchor are configured to sandwich an atrial septum between the distal end of the at least one helical leg and the at least one distal anchor leg.

Applicants appreciate the Examiner pointing out the lack of antecedent basis for certain limitations contained in dependent Claims 43, 44, 46 and 60 and have amended the claims accordingly.

Applicants have amended Claim 43 by changing the dependency of Claim 43 from Claim 33 to Claim 40. Claim 40 provides the antecedent basis for the “retrieval device” limitation recited in Claim 43.

In response to the Examiner’s indication that there is insufficient antecedent basis in Claim 44, applicants have amended the limitation “retrieval head” to “retrieval device” to clarify

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the claim and also amended the dependency from Claim 33 to Claim 41, to provide the antecedent basis for the claim limitation.

In regards to the insufficient antecedent bases noted by the Examiner in Claims 46 and 60, Applicants have changed the dependencies of each of the claims from 33 to 39 to provide the antecedent bases for “the proximal ring” and “the distal ring”. Applicants have further amended the “proximal anchor” in Claim 46 to “helical leg” for consistency with the other amendments made to Claim 33.

Response to the Rejections under 35 U.S.C. 102

Latson et al.

Claims 1, 15, 18, 25-26, 30, 33, 39-40, 42, 46, 49, 56-57 and 60 were rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,861,003 to Latson et al.

The Examiner stated that Latson disclosed a proximal anchor having at least one helical leg extending between a proximal ring and a distal ring (Figs. 2 and 6). However, Latson does not disclose a proximal anchor comprising a proximal ring, a distal ring and at least one helical leg extending from the proximal ring and distal ring. Figures 2 and 6 in Latson, for example, show that wire support frame is not in contact with sac joining connector 7 or catheter connector 8. Indeed, at Col. 4, lines 62-65, Latson states that the wire support frame 9 is not attached to the occlusion bag 4 so the wire support frame 9 can move within the occlusion bag 4 to position the occlusion bag 4 and its sacs 5,6 during deployment. By amending Claim 1 to include a proximal anchor comprising at least one helical leg that extends from the proximal ring and the distal ring, Applicants believe that Claim 1 is not anticipated by Latson et al. Applicants also submit that dependent claims 2-32, which depend from Claim 1, are each patentable for at least the same reasons that Claim 1 is patentable, and are also patentable for the unique combination of features that each claim recites.

Likewise, the Examiner stated that Latson disclosed an implant configured to be supported by the proximal and distal anchors (Fig. 2), wherein the proximal and distal anchors are configured to be movable between a collapsed and delivery position and an expanded position in which the proximal and distal anchors secure the implant to a wall of an organ within a

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patient/sandwich an atrial septum wall between at least one proximal anchor leg and at least one distal anchor leg and to support an implant in a septum wall (Figs. 2-3 and 6); and a delivery catheter configured to deploy an implant, a proximal anchor, and a distal anchor in a septum wall (Figs. 3-6). However, Latson does not disclose a system comprising an implant, a proximal anchor comprising at least one helical leg configured to expand from a compressed state to a relaxed, the at least one helical leg comprising a proximal base and a distal end and wherein the proximal anchor and the distal anchor are configured to sandwich an atrial septum wall between the distal end of the at least one helical leg and the at least one distal anchor leg and to support the implant in the septum wall. For example, Figures 2 and 6 of Latson show there is no portion of wire support frame 9 that may be characterized as a “distal end” which contacts the atrial septum 2. By amending Claim 33 to include at least one helical leg that comprises a proximal base and a distal end wherein the proximal anchor and the distal anchor are configured to sandwich an atrial septum wall between the distal end of the at least one helical leg and the at least one distal anchor leg, Applicants believe that Claim 33 is not anticipated by Latson et al. Applicants also submit that dependent claims 34-63, which depend from Claim 33, are each patentable for at least the same reasons that Claim 33 is patentable, and are also patentable for the unique combination of features that each claim recites.

Ruiz

Claims 33, 48, 56 and 58-59 were also rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,976,174 to Ruiz. The Examiner suggested that Ruiz disclosed an implant configured to be implanted within a patient (Fig. 1A); a proximal anchor comprising at least one helical leg configured to expand from a compressed state to a relaxed state (Figs. 2 and 1A); a distal anchor comprising at least one leg configured to expand from a compressed state to an expanded state (Figs. 2 and 1A); wherein a proximal anchor and a distal anchor are configured to sandwich an atrial septum wall between at least one proximal anchor leg and at least one distal anchor leg and to support an implant in a septum wall, and a delivery catheter. Ruiz, however, does not disclose a system comprising a proximal anchor comprising at least one helical leg configured to expand from a compressed state to a relaxed state, where the at least one helical leg comprises a proximal base and a distal end and wherein the proximal anchor and the distal anchor are configured to sandwich an atrial septum wall between the distal end of

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the at least one helical leg and the at least one distal anchor leg. As stated previously with respect to the Latson reference, amended Claim 33 now includes at least one helical leg that comprises a proximal base and a distal end wherein the proximal anchor and the distal anchor are configured to sandwich an atrial septum wall between the distal end of the at least one helical leg and the at least one distal anchor leg. Applicants believe that Claim 33 is not anticipated by Ruiz. Applicants also submit that dependent claims 34-63, which depend from Claim 33, are each patentable for at least the same reasons that Claim 33 is patentable, and are also patentable for the unique combination of features that each claim recites.

In view of the foregoing, Applicants respectfully submits that at least Claims 1, 15, 18, 25-26, 30, 33, 39-40, 42, 46, 48-49 and 56-60 comply with the requirements of 35 U.S.C. 102(b).

Response to the Rejections under 35 U.S.C. 103

Dependent Claims 2-13, 19-22, 24, 31, 34-38, 44, 50-53, 55 and 62 were rejected by the Examiner under 35 U.S.C. 103 as being unpatentable over Latson et al. as applied to Claims 1 and 33 above and in view of Schwartz, U.S. Patent Pub. No. 2002/0077555; Dependent Claims 14, 23, 32, 45, 54 and 63 were rejected by the Examiner under 35 U.S.C. 103 as being unpatentable over Latson et al. as applied to Claims 1 and 33 above and in view of U.S. Patent No. 6,024,756 to Huebsch et al.; and Dependent Claims 16-17, 27-29, 41 and 47 were rejected under 35 U.S.C. 103 as being unpatentable over Latson et al. as applied to Claims 16 and 25 above and in view of Ruiz.

As mentioned above, independent Claim 1 has been amended to include a proximal anchor comprising at least one helical leg that extends from the proximal ring and the distal ring. As neither Latson, Schwartz, Huebsch or Ruiz, alone or in combination, disclose a proximal anchor comprising at least one helical leg that extends from the proximal ring and the distal ring, Applicants believe that dependent Claims 2-14, 16-17, 19-24, 27-29 and 31-32 are each patentable for at least the reasons that Claim 1 is patentable, and are also patentable for the unique combination of features that each dependent claim recites.

Likewise, independent Claim 33 has been amended to include at least one helical leg that comprises a proximal base and a distal end wherein the proximal anchor and the distal anchor are configured to sandwich an atrial septum wall between the distal end of the at least one helical leg

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and the at least one distal anchor leg. Neither Latson, Schwartz, Huebsch or Ruiz, alone or in combination, disclose at least one helical leg that comprises a proximal base and a distal end wherein the proximal anchor and the distal anchor are configured to sandwich an atrial septum wall between the distal end of the at least one helical leg and the at least one distal anchor leg. For these reasons, Applicants believe that dependent Claims 34-38, 41, 44-45, 47, 50-55, 62-63 are each patentable for at least the reasons that Claim 33 is patentable, and are also patentable for the unique combination of features that each claim recites.

In view of the foregoing, Applicant respectfully submits that at least Claims 2-14, 16-17, 19-24, 27-29, 31-32, 34-38, 41, 44-45, 47, 50-55, 62-63 comply with the requirements of § 103.

CONCLUSION


Claims 1 through 63 remain pending for consideration. Based on the above amendments and remarks, Applicants submit that each of the pending claims is currently in condition for allowance. Accordingly, Applicants respectfully request a notice of allowance. Applicants have endeavored to respond to each of the issues raised by the Examiner. However, if there remain any unresolved issues that could be resolved via a telephone conference, Applicants invite the Examiner to initiate the same with Applicants' representative at the telephone number shown below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 4/25/06

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AMENDMENTS TO THE DRAWINGS

Replacement sheets for Sheet Nos. 8, 9 and 11 are provided and reflect the following amendments to the drawings:

In Sheet No. 8, reference characters 230, 231 have been added to Figure 20, and reference characters 232 and 234 have been added to Figure 21.

In Sheet No. 9, reference character 296 has been changed to 256 in Figure 22.

In Sheet No. 11, the relative positions of Figures 29 and 30 have been switched.